

Biotechnology Risk Assessment Research Grants Program

MODIFICATION: PAGE 23

2012 Request for Applications

LETTER OF INTENT RECEIPT DATE: DECEMBER 1, 2011
APPLICATION DEADLINE: FEBRUARY 1, 2012



U.S. Department of Agriculture

National Institute of Food and Agriculture

NATIONAL INSTITUTE OF FOOD AND AGRICULTURE; U.S. DEPARTMENT OF AGRICULTURE

BIOTECHNOLOGY RISK ASSESSMENT RESEARCH GRANTS PROGRAM

INITIAL ANNOUNCEMENT

CATALOG OF FEDERAL DOMESTIC ASSISTANCE: This program is listed in the Catalog of Federal Domestic Assistance under 10.219, Biotechnology Risk Assessment Research.

DATES: Letters of Intent Receipt date and time is the close of business (COB) on **Thursday, December 1, 2011** (5:00 p.m. Eastern Daylight Time). Applications must be received by close of business (COB) on **Wednesday, February 1, 2012** (5:00 p.m. Eastern Daylight Time). Applications received after this deadline will normally not be considered for funding. The agency strongly encourages applicants to submit applications well before the deadline to allow time for correction of technical errors identified by Grants.gov.

Comments regarding this request for applications (RFA) are requested within six months from the issuance of this notice. Comments received after that date will be considered to the extent practicable.

STAKEHOLDER INPUT: The National Institute of Food and Agriculture (NIFA) is requesting comments regarding this RFA from any interested party. These comments will be considered in the development of the next RFA for the program, if applicable, and will be used to meet the requirements of section 103(c)(2) of the Agricultural Research, Extension, and Education Reform Act of 1998 (7 U.S.C. 7613(c)(2)). This section requires the Secretary to solicit and consider input on a current RFA from persons who conduct or use agricultural research, education and extension for use in formulating future RFAs for competitive programs. Written stakeholder comments on this RFA should be submitted in accordance with the deadline set forth in the DATES portion of this Notice.

Written stakeholder comments should be submitted by mail to: Policy and Oversight Division; Office of Grants and Financial Management; National Institute of Food and Agriculture; USDA; STOP 2299; 1400 Independence Avenue, SW; Washington, DC 20250-2299; or via e-mail to: RFA-OGFM@nifa.usda.gov. (This e-mail address is intended only for receiving comments regarding this RFA and not requesting information or forms.) In your comments, please state that you are responding to the Biotechnology Risk Assessment Research Grants Program RFA.

EXECUTIVE SUMMARY: NIFA announces the availability of grant funds and requests applications for the Biotechnology Risk Assessment Research Grants Program (BRAG) for fiscal year (FY) 2012 to support environmental assessment research concerning the introduction of genetically engineered organisms (GE) into the environment. NIFA anticipates that the amount available for support of this program in FY 2012 will be approximately \$4 million. This RFA is being released prior to the passage of an Appropriations Act for FY 2012. Enactment of

additional Continuing Resolutions or Appropriations Act may affect the availability or level of funding for this program.

This notice identifies the objectives for BRAG projects, the eligibility criteria for projects and applicants, and the application forms and associated instructions needed to apply for a BRAG grant. NIFA additionally requests stakeholder input from any interested party for use in the development of the next RFA for this program.

IMPORTANT INFORMATION REGARDING NIFA POLICIES AND PROCEDURES:

******* PLEASE READ *******

Changes in the FY 2012 RFA. In FY 2012, a submission of a full proposal application with a corresponding LOI is strongly encouraged (with exception to conference grant applications), but not required. The time and date of receipt of a LOI is 5:00 p.m. EDT, Thursday, December 1, 2011. For instructions on how to prepare a LOI, please see Part IV, A. The deadline for submission of a full proposal application is 5:00 p.m. EDT, Wednesday, February 1, 2012.

Beginning in FY 2013, submission of a full proposal without a corresponding LOI will not be considered for review.

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PART I—FUNDING OPPORTUNITY DESCRIPTION

A. Legislative Authority and Background

Authority for the BRAG program is contained in section 1668 of the Food, Agriculture, Conservation, and Trade Act of 1990 (7 U.S.C. 5921) and amended in section 7210 of the Farm Security and Rural Investment Act of 2002 (7 U.S.C. 7901) (Pub. L. 107-171). In accordance with the legislative authority in the Farm Security and Rural Investment Act of 2002 (7 U.S.C. 7901), the BRAG program supports research designed to identify and develop appropriate management practices to minimize physical and biological risks associated with genetically engineered animals, plants, and microorganisms. NIFA and ARS of the U.S. Department of Agriculture (USDA) jointly administer the BRAG program. The administrative regulations for this program are found at 7 CFR 3415 and 7 CFR 3430.

B. Purpose and Priorities

The purpose of the BRAG program is to support the generation of new information that will assist Federal regulatory agencies in making science-based decisions about the effects of introducing into the environment genetically engineered organisms (GE), including plants, microorganisms (including fungi, bacteria, and viruses), arthropods, fish, birds, mammals and other animals excluding humans. Investigations of effects on both managed and natural environments are relevant. The BRAG program accomplishes its purpose by providing Federal regulatory agencies with scientific information relevant to regulatory issues.

The BRAG program supports applied and/or fundamental risk assessment research, which is defined as the science-based evaluation and interpretation of factual information in which a given hazard, if any, is identified, and the consequences associated with the hazard are explored. Research funded through this program will be relevant to environmental risk assessment, including biological risk, and the federal regulatory process. When evaluating GE organisms, Federal regulators must answer the following four general questions:

1. Is there a hazard? (Potential hazard identification);
2. How likely is the hazard to occur? (Quantifying the probability of occurrence; identifying likely exposure scenarios);
3. What is the severity and extent of the hazard if it occurs? (Quantifying the effects); and
4. Is there an effect above and beyond what might occur with an unmodified organism or an organism that has similar traits, but was developed using other technologies?

The BRAG program will also support risk management research, which is defined to include either: (1) research aimed primarily at reducing effects of specific biotechnology-derived agents; or (2) a policy and decision-making process that uses risk assessment data in deciding how to avoid or mitigate the consequences identified in a risk assessment.

Although project directors (PDs) are not required to perform actual risk assessments as part of the research they propose, they should design studies that will provide information useful to regulators for making science-based decisions in their assessments of genetically engineered (GE) organisms. Accordingly, applicants are encouraged to address the following questions in their applications:

- What is the relevance of this research to the evaluation of GE organisms?
- What information will be provided by this research to help regulators adequately assess GE organisms?;
- How does this research provide information or methods or model exposures useful in identifying and/or characterizing hazards associated with introducing GE organisms into the environment?

Applications to the BRAG program must address one of the following program areas or seek partial funding for a conference that addresses science-based risk assessment or risk management of GE organisms released into the environment (See Part I, C. for more detailed descriptions.):

1. Research designed to identify and develop appropriate management practices to minimize physical and biological risks to the environment associated with GE animals, plants, and microorganisms;
2. Research designed to develop methods to monitor the dispersal of GE animals, plants, and microorganisms;
3. Research designed to further existing knowledge with respect to the characteristics, rates, and methods of gene transfer that may occur between GE animals, plants, and microorganisms, and related wild and agricultural organisms;
4. Environmental assessment research designed to provide analysis which compares the relative impacts of animals, plants, and microorganisms modified through genetic engineering to other types of production systems; or
5. Other areas of research designed to further the purposes of the BRAG program.

Awards will not be made for food safety risk assessment or risk management, health risk assessment or risk management of humans or domestic food animals exposed to GE organisms, social or economic research, methods for seed storage, clinical trials, commercial product development, product marketing strategies, product stewardship, or other research deemed inappropriate to risk assessment or risk management relative to the environment.

C. Program Area Description

Program Area Code – HX

Letters of Intent Receipt - Thursday, December 1, 2011 (5:00 p.m., EDT)

Application Deadline – Wednesday, February 1, 2012 (5:00 p.m., EDT)

Proposed Budget Requests –

Priority Research Proposals **must not exceed \$1,000,000** total (including indirect costs) for project periods of up to 4 years.

Standard Research Proposals **must not exceed \$500,000** total (including indirect costs) for project period up to 4 years.

Conference Proposals **must not exceed \$25,000** total (no indirect costs are allowed on conference grants).

Requested Project Type – Research Projects

Program Area Contacts:

Dr. Shing Kwok (202-401-6060, skwok@nifa.usda.gov), National Program Leader; Plant Systems-Production; Institute of Food Production and Sustainability; National Institute of Food and Agriculture.

Dr. Mark Mirando (202-401-4336, mmirando@nifa.usda.gov), National Program Leader; Animal Systems; Institute of Food Production and Sustainability; National Institute of Food and Agriculture.

Dr. Jack Okamuro (301-504-5912, mobile: 202-285-9520; jack.okamuro@ars.usda.gov), National Program Leader; Crop Production and Protection; Agricultural Research Service.

NIFA and ARS will competitively award research grants to support science-based biotechnology regulation, thereby helping to address concerns about the effects of introducing genetically engineered (GE) organisms into the environment and helping regulators to develop policies regarding such introduction. The BRAG program also encourages proposals seeking partnership with or involvement of international entities where appropriate and domestically beneficial. In addition, the BRAG program is accepting proposals seeking partial funding for a conference that addresses science-based risk assessment or risk management of GE organisms released into the environment.

PRIORITY RESEARCH PROPOSALS

A priority research project would apply trans-disciplinary and, where appropriate, multi-state and multi-institutional approaches to provide viable solutions to the highest priority issues in biotechnology risk assessment research. A priority award under the BRAG program should encourage maximum flexibility in biotechnology risk assessment and risk management. The

research team for a priority grant should be comprised of members working in discovery and learning and should conduct trans-disciplinary research in an emerging or priority area in biotechnology risk assessment research. Priority research proposals may be focused on applied and/or fundamental research projects.

Areas of interest to the BRAG program for a priority grant are the following:

1. Comparison between Transformation-associated Mutagenesis in Plants and Variation Introduced Using Non-genetic Engineering Approaches

Comparison of the types, frequency, and effects of mutations associated with transformation and other plant breeding techniques, to support assessment of the potential for unintended effects to occur during genetic engineering. Proposed projects must be designed to obtain, analyze, and compare data concerning the types and frequencies of genomic sequence changes and associated phenotypic effects generated by

- (a) Insertion of DNA with one or more widely used genetic engineering techniques (e.g., particle bombardment, *Agrobacterium*-mediated transformation), and
- (b) One or more other mutation-generating plant breeding techniques (e.g., irradiation or chemical mutagenesis, somatic cell culture and clonal propagation, ploidy alterations, wide interspecies crosses, induced chromosomal translocation).

Proposed projects must be conducted in a commercially significant crop species and their experimental designs must generate statistically relevant data.

2. Studies of Landscape Level Environmental Impacts of GE crops

Identification and experimental assessment of potential environmental impacts of large-scale growth of GE crops, with emphasis on crops used for biofuels (e.g., perennial species such as trees or grasses), to support the development of a risk assessment framework. Project must address multiple BRAG topic areas, preferentially chosen from among the following:

- (a) Strategies for conducting large scale GE field studies with minimal environmental risk;
- (b) Impacts on ecosystem function and services;
- (c) Landscape level studies of environmental impacts of land use changes;
- (d) Assessment and documentation of significant community or ecosystem effects not revealed by studies on small plots, such as effects on plant or animal communities, species displacement, soil health, hydrology, water quality, fertilizer, pesticide, and soil amendment inputs, toxicant and pesticide residue levels;
- (e) Assessment of the likelihood and impact of gene flow to related organisms under various management strategies;
- (f) Basic biology and ecology of the species; and
- (g) Weediness or invasiveness of the GE organism.

3. Pollen Flow and Best Management Practices for Co-existence

De-regulation of a genetically engineered (GE) crop (e.g. alfalfa, sugar beet, or switchgrass) involves an evaluation of pollen flow biology and assessment in each plant species. This priority focuses on research that will provide science-based information regarding gene flow in GE crops and/or development of the best management practices for co-existence with non GE crops. Research should focus on, but not limited to, pollen flow biology (e.g., pollen flow dynamics, pollen stability/viability, etc.) and/or developing strategies to restrict transgene transfer, including pollen flow restriction strategies.

Priority Research Proposals must not exceed \$1,000,000 total (including indirect costs) for project periods of up to four years.

STANDARD RESEARCH PROPOSALS

Proposals that address issues related to newly developed GE organisms (e.g., trees and other perennials, including biofuel crops are especially sought). Research proposals can be applied and/or fundamental and must address one of the following five program areas:

1. Management Practices to Minimize Environmental Risk

Research designed to identify and develop appropriate management practices to minimize physical and biological risks to the environment associated with GE animals, plants, and microorganisms. Potential areas of research include, but are not limited to:

- (a) Evaluation of management, monitoring, and mitigation methodologies for confinement of field trials of GE organisms;
- (b) Development of management methodologies for reducing the spread of GE organisms into natural and managed environments, and assessments of the stability and efficacy of such methodologies in field environments;
- (c) Assessing environmental impact and molecular effects of multi-transgenic stacked traits in transgenic organisms;
- (d) Defining and assessing pathways of and parameters for environmental exposure from GE imports for food, feed or processing;
- (e) Development of effective bioconfinement strategies, and evaluation of the efficacy of genetic techniques, to prevent gene transfer or outcrossing;
- (f) Assessing the effects and effectiveness of reproductive or breeding containment strategies such as sterilization or mono-sexing transgenic animals; and/or

(g) Mitigation measures to limit gene introgression when: transgenic animals are released or escape into the environment, physical containment fails, or biological containment is unavailable.

2. Methods to Monitor Dispersal of GE Organisms

Research designed to develop methods to monitor the dispersal of GE animals, plants, and microorganisms. Potential areas of research include, but are not limited to:

(a) Assessing the effects of transgene(s) in engineered animal species that may easily spread such as birds, aquatic species, arthropods and other invertebrates. This area may include:

- Studies of transgene stability over multiple generations,
- Comparative mating competence or reproductive studies,
- Juvenile and adult viability studies, and/or
- Comparative behavior and biological studies, including studies addressing whether transgenes can alter host range or ecological interactions;

(b) Survivability profiles and/or fitness of transgenic organisms in the wild; and/or

(c) Strategies for large-scale deployment or field studies of GE organisms with special reference to those considerations that may not be revealed through small-scale evaluations and tests.

3. Gene Transfer to Domesticated and Wild Relatives

Research designed to further existing knowledge with respect to the characteristics, rates, and methods of gene transfer that may occur between GE animals, plants, and microorganisms, and related wild and agricultural organisms. Potential areas of research include, but are not limited to:

(a) Impacts of gene flow from transgenic plants, insects, animals, or microorganisms to related organisms, communities, or ecosystems. Gene flow research should be directed to organisms with a high potential for outcrossing to sexually compatible plant species, gene flow to feral or wild relatives, or for gene introgression (e.g., those species with high rates of outcrossing) and to genes that have a high potential for altering the fitness of the recipient organism for its environment. With regard to plants, preference will be given to studies with species that have sexually compatible wild relatives in the United States;

(b) Fate and stability (persistence) of transgenes that have been introgressed by outcrossing into populations of non-transgenic organisms, and the degree to which they confer a selective advantage or disadvantage upon the carriers, especially with regard to transgenes that confer enhanced growth or abiotic stress tolerance;

(c) Measuring impact of transgene placement (nuclear or cytoplasmic) on the transfer and introgression of transgenes into wild and feral plants, animals, or fungi especially as a means of confinement;

(d) Assessing the influence of genetic background on the expression of and phenotypes conferred by regulatory genes; and/or

(e) Data acquisition and modeling of transgene or transgenic organism escape into the environment, including modeling to identify parameters that influence gene dispersal and its consequences, with a particular interest in insect-mediated gene movement. Model development should include and testing of the model's robustness and outcomes over large temporal-spatial scales and different environments.

4. Environmental Impacts of GE relative to non-GE Production Systems

Environmental assessment research designed to provide analysis which compares the relative impacts of animals, plants, and microorganisms modified through genetic engineering to other types of production systems. Potential areas of research include, but are not limited to:

- (a) Elucidation of the influence of genetically-engineered crops on ecosystem function including bioenergy crops and other crops engineered for pharmaceutical/industrial production, agronomic trait enhancement, pest resistance, herbicide resistance, etc.;
- (b) Landscape level studies of the environmental impacts of land use changes enabled by genetic engineering of biofuel crops;
- (c) Assessment of the use of transgenic as compared to non-transgenic organisms on the impacts of agricultural or forest management systems (e.g., on community structures of agro- or forest ecosystems). Important focus areas are:
 - The presence and function of various types of beneficial organisms,
 - Defining the magnitude of changes in indicator species or communities that could trigger concerns regarding ecosystem impacts, and/or
 - How the biology and ecology of indicator taxa are influenced by geography, seasonal fluctuations, species, etc.);
- (d) Assessment of how the introduction of transgenic organisms alters the impact of agriculture on the rural environment. Documentation of significant off-site community or ecosystem effects that are not revealed by studies on small plots (including both beneficial and detrimental effects), such as altered land use practices or other aspects of human ecology, species displacement, soil erosion, effects on water quality, or other geographically dispersed events. There is a need to identify appropriate sample size, plot size, study duration, and positive and negative controls, including consideration of specific pesticides in conventional agronomic practices, untreated control plots, or organic production systems;
- (e) Comparative management techniques and resources for maintenance of non-transgenic animals versus transgenic animals (e.g., changes in land use or manure management practices required for transgenic animals engineered to utilize feed more efficiently);

- (f) Comparative assessment of environmental and economic impacts of agricultural production systems using conventional and organic methods involving plant, animal or microbial biotechnology. Appropriate parameters or metrics are to include, but are not limited to:
- Community structure,
 - Fertilizer, pesticide, and soil amendment inputs,
 - Non-target impacts,
 - Changes in toxicant and pesticide residue levels,
 - Prevalence and distribution of herbicide tolerant weeds,
 - Soil health, and/or
 - Land use related to yield and productivity;
- (g) Assessment of the impacts of genetic engineering on plant-pest interactions, including impacts on the plants themselves and on plant-pest populations; and/or
- (h) Development and/or evaluation of tools for assessing weediness or invasiveness of GE plants relative to unmodified parent organisms.

5. Other Research Topics

Other areas of research designed to further the purposes of the BRAG Program. Potential areas of research include, but are not limited to:

- (a) Comparative assessment of the effects of GE plants with either a single resistance gene vs. stacked/pyramided resistance genes or single resistance gene vs. multiple genes that confer broad resistance to insects and/or diseases. Research focus areas may include:
- The impact of gene stacking on non-target species,
 - The effects of stacked genes on pest populations, and/or
 - Ecological significance and practices needed to manage weedy hosts that have stacked resistance genes to insects and/or diseases.

Proposals on pest resistance management are not excluded from the program, but any such proposals submitted should describe a clear and significant connection with biotechnology risk assessment/management.

- (b) Biological and ecological studies associated with GE perennial species. Studies may focus on:
- Gene flow,
 - Environmental risk persistence,
 - Dormancy, and other fitness characteristics,
 - Ecosystem interactions and potential ecosystem changes when grown in new settings, and/or
 - Ecological effects of technologies for reducing the undesired spread of GE organisms;

(c) Development of environmental risk assessment methodologies for GE organisms when there is little baseline data on the unmodified parent organism (e.g., *Panicum virgatum*, *Miscanthus*, *Populus* spp., *Eucalyptus* spp.); and/or

(d) Assessment of the potential for non-target effects of RNA interference transgenes.

Standard Research Proposals must not exceed \$500,000 total (including indirect costs) for project periods of up to four years.

CONFERENCE PROPOSALS

Applicants to the BRAG program may request partial funding to organize a conference that brings together scientists, regulators, and other stakeholders to review the science-based data relevant to science-based risk assessment or risk management of GE organisms released into the environment. To be eligible for funding, the steering committee for the proposed conference should include representatives from a variety of relevant scientific disciplines, such as ecology, population biology, pathology, production and resource management science, as well as educators, extension specialists and others, as appropriate.

BRAG conference applications should: 1) describe the relevance of the proposed conference to agricultural biotechnology risk assessment and/or risk management in the United States, 2) explain the uniqueness and timeliness of the conference, 3) outline the qualifications of the organizing committee and the appropriateness of the invited speakers to the topic areas to be covered, 4) state clearly the goals of the conference and the likely outcomes, 5) explain the need for the various elements of the budget, and 6) describe the means by which the organizers will make up the total costs of the conference from other sources.

The goals for the conference should include sharing of scientific information and identification of gaps in knowledge, and/or public education and outreach, among others. Publication of the proceedings will be required.

Conference Proposals must not exceed \$25,000 total (no indirect costs are allowed on conference grants).

PART II—AWARD INFORMATION

A. Available Funding

There is no commitment by USDA to fund any particular application or to make a specific number of awards. Subject to the availability of funds, NIFA anticipates that approximately \$4.0 million will be available to fund applications in FY 2012. This RFA is being released prior to the passage of an Appropriations Act for FY 2012. Enactment of additional Continuing Resolutions or Appropriations Act may affect the availability or level of funding for this program.

Awards issued as a result of this RFA will have designated the Automated Standard Applications for Payment System (ASAP), operated by the Department of Treasury's Financial Management Service, as the payment system for funds. For more information see http://www.nifa.usda.gov/business/method_of_payment.html.

B. Types of Applications

In FY 2012, applications may be submitted to the BRAG Program as one of the following four types of requests:

(1) New application. This is a project application that has not been previously submitted to the BRAG Program. All new applications will be reviewed competitively using the selection process and evaluation criteria described in Part V—Application Review Requirements.

(2) Renewal application. This is a project application that requests additional funding for a project beyond the period that was approved in an original or amended award. Applications for renewed funding must contain the same information as required for new applications, and additionally must contain a Progress Report (see Project Narrative, Part IV). Renewal applications must be received by the relevant due dates, will be evaluated in competition with other pending applications in appropriate area to which they are assigned, and will be reviewed according to the same evaluation criteria as new applications.

(3) Resubmitted application. This is an application that had previously been submitted to the BRAG Program but not funded. Project Directors (PDs) must respond to the previous review panel summary (see Response to Previous Review, Part IV). Resubmitted applications must be received by the relevant due dates, will be evaluated in competition with other pending applications in appropriate area to which they are assigned, and will be reviewed according to the same evaluation criteria as new applications.

(4) Resubmitted renewal application. This is a project application that requests additional funding for a project beyond the period that was approved in the original award. In addition, this is an application that had previously been submitted for renewal to the BRAG Program but not funded. Therefore, PDs must provide a Progress Report as required under the Project Narrative, Part IV, and must respond to the previous review panel summary as required under Response to Previous Review, Part IV. Resubmitted renewal applications must be received by the relevant

due dates, will be evaluated in competition with other pending applications in appropriate areas to which they are assigned, and will be reviewed according to the same evaluation criteria as new applications.

C. Project Types

Priority research proposals submitted to the BRAG program **should not exceed \$1 million (including indirect costs)** for project periods of up to 4 years of support. Standard research proposals **should not exceed \$500,000 (including indirect costs)** for project periods of up to 4 years of support. Conference proposals **should not exceed \$25,000 (no indirect costs are allowed on conference grants)**. Proposal requests exceeding these limits will be excluded from review.

Project periods for Research grants cannot exceed five years, the statutory time limit.

The BRAG program will not support applications for postdoctoral fellowships.

PART III—ELIGIBILITY INFORMATION

A. Eligible Applicants

Applications may be submitted by any United States public or private research or educational institution or organization. Award recipients may subcontract to organizations not eligible to apply provided such organizations are necessary for the conduct of the project. An applicant's failure to meet an eligibility criterion by the time of an application deadline may result in the application being excluded from consideration or, even though an application may be reviewed, will preclude NIFA from making an award.

B. Cost Sharing or Matching

NIFA does not require matching support for this program. Applications shall be peer reviewed and selected for funding without regard to matching resources.

PART IV—APPLICATION AND SUBMISSION INFORMATION

A. Letter of Intent Instructions

In FY 2012, the BRAG program **strongly encourages** a Letter of Intent (LOI) for submission of an application.

Please follow the guidelines below for LOI submission requirements

1. The Letter of Intent must adhere to the following formatting guidelines:
 - a. Font size must be at least 12 point
 - b. Margins must be at least one inch in all directions
 - c. Line spacing must not exceed six lines of text per vertical inch
2. The Letter of Intent is limited to **two pages** for all project and grant types.
 - a. On Page 1 provide **only** the following information:
 - i. the name, professional title, department, institution, and *e*-mail address of the lead project director (PD) and name, professional title, department, and institution of all collaborating investigators
 - ii. the Program Area or the Priority Area that is most closely addressed in the application
 - b. On Page 2 include:
 - i. a descriptive title
 - ii. rationale
 - iii. overall hypothesis or goal
 - iv. specific objectives
 - v. approach
 - vi. potential impact and expected outcomes
3. NIFA will only accept Letters of Intent in the portable document format (PDF). Attach the PDF Letter of Intent to an e-mail addressed to Dr. Shing Kwok (skwok@nifa.usda.gov) for Submission of Letter of Intent. In the e-mail subject line, write: Letter of Intent [ProgramArea Code] _ [PDs Last Name].
4. A letter is strongly encouraged for **all** grant types except Conference Grant applications.
5. Submission of more than one Letter of Intent to a program is discouraged.
6. An acknowledgement receipt will be sent by replying to the sender within 5 business days.
7. Letters of Intent will be reviewed by scientific program staff in order to plan for appropriate expertise for the peer review panel and ensure that the proposed project fits appropriately within the Program Area Priorities.
8. Applicants must notify the appropriate Program Area Contact of any changes to project key personnel, title, or objectives from the Letter of Intent to the submission of a full application.

B. Electronic Application Package

Only electronic applications may be submitted via Grants.gov to NIFA in response to this RFA. **Applicants are advised to submit early to the Grants.gov system.**

New Users of Grants.gov

Prior to preparing an application, it is suggested that the PD/PI first contact an Authorized Representative (AR) (also referred to as Authorized Organizational Representative or AOR) to determine if the organization is prepared to submit electronic applications through Grants.gov. If the organization is not prepared (e.g., the institution/organization is new to the electronic grant application process through Grants.gov), then the one-time registration process must be completed PRIOR to submitting an application. It can take as much as two weeks to complete the registration process so it is critical to begin as soon as possible. In such situations the AR should go to **“Get Registered” on the Grants.gov left navigation bar (or go to http://www.grants.gov/applicants/get_registered.jsp) for information on registering the institution/organization with Grants.gov. A quick reference guide listing the steps is available as a 4-page PDF document at the following website: <http://grants.gov/assets/Grants.govRegistrationBrochure.pdf>.**

Steps to Obtain Application Package Materials

The steps to access application materials are as follows:

1. In order to access, complete and submit applications, applicants must download and install a version of Adobe Reader compatible with Grants.gov. This software is essential to apply for NIFA Federal assistance awards. For basic system requirements and download instructions, please see http://www.grants.gov/help/download_software.jsp. To verify that you have a compatible version of Adobe Reader, Grants.gov established a test package that will assist you in making that determination. Grants.gov Adobe Versioning Test Package: <http://www.grants.gov/applicants/AdobeVersioningTestOnly.jsp>.
2. The application package must be obtained via Grants.gov, go to www.grants.gov, click on “Apply for Grants” in the left-hand column, click on **“Step 1: Download a Grant Application Package and Instructions,”** enter the funding opportunity number **USDA-NIFA-BRAP-003604** in the appropriate box and click “Download Package.” From the search results, click “Download” to access the application package.

Contained within the application package is the “NIFA Grants.gov Application Guide: A Guide for Preparation and Submission of NIFA Applications via Grants.gov.” This Guide contains an introduction and general Grants.gov instructions, information about how to use a Grant Application Package in Grants.gov, and instructions on how to complete the application forms.

If assistance is needed to access the application package (e.g., downloading or navigating Adobe forms), **or to submit the application** then refer to resources available

on the Grants.gov Web site first (www.grants.gov). Grants.gov assistance is also available as follows:

Grants.gov customer support

Toll Free: 1-800-518-4726

Business Hours: 24 hours a day, 7 days a week. Closed on Federal Holidays.

Email: support@grants.gov

See <http://www.nifa.usda.gov/funding/electronic.html> for additional resources for applying electronically.

C. Content and Form of Application Submission

Electronic applications should be prepared following Part V and VI of the document entitled “A Guide for Preparation and Submission of NIFA Applications via Grants.gov.” This guide is part of the corresponding application package (see Section A. of this Part). The following is **additional information** needed in order to prepare an application in response to this RFA. **If there is discrepancy between the two documents, the information contained in this RFA is overriding.**

Note the attachment requirements (e.g., portable document format) in Part III section 3. of the Guide. **ANY PROPOSALS CONTAINING NON-PDF DOCUMENTS WILL BE AT RISK OF BEING EXCLUDED FROM NIFA REVIEW.** Partial applications will be excluded from NIFA review. With documented prior approval, resubmitted applications will be accepted until close of business on the closing date in the RFA.

If you do not own PDF-generating software, Grants.gov provides online tools to assist applicants. Users will find a link to “Convert Documents to PDF” on http://grants.gov/help/download_software.jsp#pdf_conversion_programs.

For any questions related to the preparation of an application please review the NIFA Grants.gov Application Guide and the applicable request for applications. If assistance is still needed for preparing application forms content, contact:

- Email: electronic@nifa.usda.gov
- Phone: 202-401-5048
- Business hours: Monday through Friday, 7:00 am – 5:00 pm Eastern Time, excluding Federal holidays.

1. SF 424 R&R Cover Sheet

Information related to the questions on this form is dealt with in detail in Part V, 2. of the NIFA Grants.gov Application Guide.

2. SF 424 R&R Project/Performance Site Location(s)

Information related to the questions on this form is dealt with in detail in Part V, 3. of the NIFA Grants.gov Application Guide.

3. R&R Other Project Information Form

Information related to the questions on this form is dealt with in detail in Part V, 4. of the NIFA Grants.gov Application Guide.

a. Field 7. Project Summary/Abstract. The summary should also include the relevance of the project to the goals of the BRAG program. Please find the suggested Project Summary/Abstract Template at: http://www.nifa.usda.gov/home/faq_apply.html#abstract .

b. Field 8. Project Narrative.

PLEASE NOTE: The Project Narrative shall not exceed eighteen (18) pages of written text including figures and tables regardless of whether it is single or double spaced. Use an easily readable font face (e.g., Geneva, Helvetica, Times New Roman). This maximum page limit has been established to ensure fair and equitable competition. The Project Narrative must include all of the following:

(1) Introduction. A clear statement of the long-term goals and supporting objectives of the proposed project should preface the project description. The most significant published work in the field under consideration, including the work of key project personnel on the current application, should be reviewed. The current status of research in the particular scientific field also should be described.

(2) Progress report. Renewal applications and resubmitted renewal applications (as described in Part II, B.) should include a clearly marked performance report describing results to date from the previous award. This section should contain the following information: (1) a comparison of actual accomplishments with the goals established for the previous award; (2) the reasons established goals were not met, if applicable; and (3) a listing of any publications resulting from the previous award. Copies of reprints or preprints may be included in the Appendices to Project Narrative portion of the submission.

(3) Rationale and significance. Present concisely the rationale for the proposed project. The project's specific relationship and relevance to the program area in which an application is submitted (see Part I, C.) and its specific relationship and relevance to potential regulatory issues of United States biotechnology research should be shown clearly. Any novel ideas or contributions that the proposed project offers should also be discussed in this section.

(4) Experimental plan. The hypotheses or questions being asked and the methodology to be applied to the proposed project should be stated explicitly. Specifically, this section must include: (1) a description of the investigations and/or experiments proposed and the sequence in which the investigations or experiments are to be performed; (2) techniques to be used in carrying out the proposed project, including the feasibility of the techniques; (3) results expected; (4) means by which experimental data will be analyzed or interpreted; (5) pitfalls that may be encountered; (6) limitations to proposed procedures; and (7) a tentative schedule for conducting major steps involved in these investigations and/or experiments.

In the experimental plan, the applicant must explain fully any materials, procedures, situations, or activities that may be hazardous to personnel (whether or not they are directly related to a

particular phase of the proposed project), along with an outline of precautions to be exercised to avoid or mitigate the effects of such hazards.

a. Field 9. Bibliography & References Cited. All work cited, including that of key personnel, should be referenced in this section of the application.

b. Field 12. Other Attachments:

1. Response to Previous Review. This requirement only applies to “Resubmitted Applications” and “Resubmitted Renewal Applications” as described in Part II, B. PDs must respond to the previous review panel summary on no more than one (1) page, titled “RESPONSE TO PREVIOUS REVIEW.”

2. Cooperation and Institutional Units Involved. Cooperative, multi-institutional and multidisciplinary applications are encouraged. Where applicable, identify each institutional unit contributing to the project and designate the lead institution or institutional unit. Clearly define the programmatic roles, responsibilities and budget for each institutional partner.

3. Appendices to Project Narrative. Appendices to the Project Narrative are allowed if they are directly germane to the proposed project. The addition of appendices should not be used to circumvent the text and/or figures and tables page limitations.

4. Collaborative Arrangements. If it will be necessary to enter into formal consulting or collaborative arrangements with others, such arrangements should be fully explained and justified. If the consultants or collaborators are known at the time of application, a vitae or resume and Statement of Work (SOW) should be provided. In addition, evidence (e.g., letter of support) should be provided that the collaborators involved have agreed to render these services. The applicant also will be required to provide additional information on consultants and collaborators in the budget portion of the application.

4. R&R Senior/Key Person Profile (Expanded)

Information related to the questions on this form is dealt with in detail in Part V, 5. of the NIFA Grants.gov Application Guide. The number of Co-PDs is limited to eight (8). Please do not list more than this number.

Also, **you must attach** ‘Current and Pending Support’ information (see NIFA Grants.gov Application Guide p. 33, item 5.3, for guidelines and a suggested format) for each senior/key person identified above. Please find suggested Current and Pending Support Template at: http://www.nifa.usda.gov/home/faq_apply.html#current. **Note: Even if no other funding is currently reported under the ‘Active’ section of this attachment, you must still list information for this grant application under the ‘Pending’ section of this attachment for each senior/key person identified above. Also note: The salary amounts requested for Senior/Key personnel should be below or commensurate with the stated time commitment listed on the Current and Pending Form. A person cannot draw a salary amount for time on the project which exceeds the time committed on the Current and Pending Form.**

5. R&R Personal Data – As noted in Part V, 6. of the NIFA Grants.gov Application Guide, the submission of this information is voluntary and is not a precondition of award. If completing the information, **do not enter any data in the field requesting the social security number.**

6. R&R Budget

Information related to the questions on this form is dealt with in detail in Part V, 7 of the NIFA Grants.gov Application Guide.

If a project is funded, beginning in the second year of funding, the project director will be required to attend annual investigator meetings either in the metropolitan Washington, DC area or another location (to be determined at a later date) for the duration of the award. Reasonable travel expenses should be included as part of the project budget.

Matching. NIFA does not require matching support for this program and matching resources will not be factored into the review process as evaluation criteria.

7. Supplemental Information Form

Information related to the questions on this form is dealt with in detail in Part VI, 1. of the NIFA Grants.gov Application Guide.

a. Field 2. Program Code. Enter the program code name “**Biotechnology Risk Assessment**” and the program code “**HX**”.

b. Field 8. Conflict of Interest List. Conflict of interest information is required for each senior/key person included in the R&R Senior/Key Person Profile. Please find the suggested Conflict of Interest Template at: http://www.nifa.usda.gov/home/faq_apply.html#coi.

D. Submission Dates and Times

Instructions for submitting an application are included in Part IV, Section 1.9 of the NIFA Grants.gov Application Guide.

Applications must be received by Grants.gov by COB on **Wednesday, February 1, 2012** (5:00 p.m. Eastern Daylight Time). Applications received after this deadline will normally not be considered for funding. The agency strongly encourages applicants to submit applications well before the deadline to allow time for correction of technical errors identified by Grants.gov.

Applicants who have problems with the submission of an application to Grants.gov are encouraged to FIRST contact the Grants.gov Help Desk to resolve any problems. Keep a record of any such correspondence. See Part IV. A. for Grants.gov contact information.

Correspondence regarding submitted applications will be sent using e-mail. Therefore, applicants are strongly encouraged to provide accurate e-mail addresses, where designated, on the SF-424 R&R Application for Federal Assistance.

If the AR has not received correspondence **from NIFA** regarding a submitted application within 30 days of the established deadline, please contact the Program Contact identified in Part VII of the applicable RFA and request the proposal number assigned to the application. **Failure to do so may result in the application not being considered for funding by the peer review panel. Once the application has been assigned a proposal number, this number should be cited on all future correspondence.**

E. Funding Restrictions

The use of grant funds to plan, acquire, or construct a building or facility is not allowed under this program. With prior approval, and in accordance with the cost principles set forth in the Office of Management and Budget (OMB) Circular No. A-21, (codified at 2 CFR 220), some grant funds may be used for minor alterations, renovations, or repairs deemed necessary to retrofit existing teaching or research spaces in order to carry out a funded project. However, requests to use grant funds for such purposes must demonstrate that the alterations, renovations, or repairs are essential to achieving the major purpose of the project. Grant funds may not be used for endowment investing.

Section 720 of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Programs (HR 112-284), limits indirect costs to 30 percent of the total Federal funds provided under each award. Therefore, when preparing budgets, applicants should limit their requests for recovery of indirect costs to the lesser of their institution's official negotiated indirect cost rate or the equivalent of 30 percent of total Federal funds awarded.

F. Other Submission Requirements

The applicant should follow the submission requirements noted in the document entitled "A Guide for Preparation and Submission of NIFA Applications via Grants.gov."

Described below are the requirements for successful submission of an application, all of the following steps must be met for an application to be considered for peer review:

- 1) Meeting the deadline: To electronically send the application to Grants.gov the submit button is hit, which triggers a date and time stamp on the application. The date and time stamp is used to determine whether the application was received by Grants.gov before the deadline, which is prior to close of business (5:00 p.m. Eastern Daylight Time) on **Wednesday, February 1, 2012**. An application submitted or resubmitted after the deadline is late. Consideration of late applications is only given in extenuating circumstances (e.g., natural disasters, confirmed Grants.gov outage) with proper documentation and support of the Agency Contact (see Part VII). The occurrence of one of these situations does not automatically ensure that a late application will be accepted. If an applicant wants a late application considered under an extenuating circumstance, the applicant should contact the Agency Contact accordingly.
- 2) Successful Grants.gov validation: The Grants.gov system performs a limited check of the application, and applicants are notified by Grants.gov of the outcome of the initial

review. Applications meeting Grants.gov requirements are made available to the funding agency for further processing. Applications that fail Grants.gov validation may be resubmitted to Grants.gov if the original agency deadline has not passed. (Note that the Grants.gov system may allow applications to be submitted after the deadline has passed, but the application is considered late by NIFA.)

- 3) Successful Agency validation: NIFA staff perform precursory review of the application. The agency validation process includes, for example, meeting eligibility requirements and following agency application guidelines (e.g., formatting, page limitations, limits on budget requests). Applicants are notified by NIFA of the outcome of this review.

PART V—APPLICATION REVIEW REQUIREMENTS

A. General

Each application will be evaluated in a 2-part process. First, each application will be screened to ensure that it meets the administrative requirements as set forth in this RFA. Second, applications that meet these requirements will be technically evaluated by a review panel.

Reviewers will be selected based upon training and experience in relevant scientific, extension, or education fields, taking into account the following factors: (a) The level of relevant formal scientific, technical education, or extension experience of the individual, as well as the extent to which an individual is engaged in relevant research, education, or extension activities; (b) the need to include as reviewers experts from various areas of specialization within relevant scientific, education, or extension fields; (c) the need to include as reviewers other experts (e.g., producers, range or forest managers/operators, and consumers) who can assess relevance of the applications to targeted audiences and to program needs; (d) the need to include as reviewers experts from a variety of organizational types (e.g., colleges, universities, industry, state and Federal agencies, private profit and non-profit organizations) and geographic locations; (e) the need to maintain a balanced composition of reviewers with regard to minority and female representation and an equitable age distribution; and (f) the need to include reviewers who can judge the effective usefulness to producers and the general public of each application.

B. Evaluation Criteria

The evaluation criteria below will be used in reviewing applications submitted in response to this RFA:

The evaluation criteria identified in 7 CFR 3415.15 (see below) will be used to review all applications submitted in response to this RFA except applications that seek funding for conferences.

Criteria for Evaluating Priority and Standard Research Applications:

1. Scientific merit of the proposal.

- ☐ Conceptual adequacy of hypothesis;
- ☐ Clarity and delineation of objectives;
- ☐ Adequacy of the description of the undertaking and suitability and feasibility of methodology;
- ☐ Demonstration of feasibility through preliminary data;
- ☐ Probability of success of project;
- ☐ Novelty, uniqueness and originality; and
- ☐ Appropriateness to regulation of biotechnology and risk assessment.

2. Qualifications of proposed project personnel and adequacy of facilities.

- ☐ Training and demonstrated awareness of previous and alternative approaches to the problem identified in the proposal, and performance record and/or potential for future accomplishments;
- ☐ Time allocated for systematic attainment of objectives;

- ☐ Institutional experience and competence in subject area; and
- ☐ Adequacy of available or obtainable support personnel, facilities, and instrumentation.

3. Relevance of project to solving biotechnology regulatory uncertainty for United States agriculture.

- ☐ Scientific contribution of research in leading to important discoveries or significant breakthroughs in announced program areas; and
- ☐ Relevance of the risk assessment research to agriculture and environmental regulations.

Criteria for Evaluating Scientific Research Conference Applications:

1. Relevance and timeliness of topics and selection of appropriate speakers;
2. General format of the conference, especially with regard to its appropriateness for fostering scientific exchange and/or public understanding;
3. Provisions for wide participation from the scientific and regulatory community and others, as appropriate;
4. Qualifications of the organizing committee;
5. Appropriateness of the budget requested; and
6. Qualifications of project personnel.

C. Conflicts of Interest and Confidentiality

During the peer evaluation process, extreme care will be taken to prevent any actual or perceived conflicts of interest that may impact review or evaluation. For the purpose of determining conflicts of interest, the academic and administrative autonomy of an institution shall be determined by reference to the current Higher Education Directory, published by Higher Education Publications, Inc., 6400 Arlington Boulevard, Suite 648, Falls Church, Virginia 22042. Phone: (703) 532-2300. Web site: <http://www.hepinc.com/>.

Names of submitting institutions and individuals, as well as application content and peer evaluations, will be kept confidential, except to those involved in the review process, to the extent permitted by law. In addition, the identities of peer reviewers will remain confidential throughout the entire review process. Therefore, the names of the reviewers will not be released to applicants.

D. Organizational Management Information

Specific management information relating to an applicant shall be submitted on a one time basis, with updates on an as needed basis, as part of the responsibility determination prior to the award of a grant identified under this RFA, if such information has not been provided previously under this or another NIFA program. NIFA will provide copies of forms recommended for use in fulfilling these requirements as part of the pre-award process. Although an applicant may be

eligible based on its status as one of these entities, there are factors which may exclude an applicant from receiving Federal financial and nonfinancial assistance and benefits under this program (e.g., debarment or suspension of an individual involved or a determination that an applicant is not responsible based on submitted organizational management information).

PART VI—AWARD ADMINISTRATION

A. General

Within the limit of funds available for such purpose, the awarding official of NIFA shall make grants to those responsible, eligible applicants whose applications are judged most meritorious under the procedures set forth in this RFA. The date specified by the awarding official of NIFA as the effective date of the grant shall be no later than September 30 of the Federal fiscal year in which the project is approved for support and funds are appropriated for such purpose, unless otherwise permitted by law. It should be noted that the project need not be initiated on the grant effective date, but as soon thereafter as practical so that project goals may be attained within the funded project period. All funds granted by NIFA under this RFA shall be expended solely for the purpose for which the funds are granted in accordance with the approved application and budget, the regulations, the terms and conditions of the award, the applicable Federal cost principles, and the Department's assistance regulations (parts 3015 and 3019 of 7 CFR).

B. Award Notice

The award document will provide pertinent instructions and information including, at a minimum, the following:

- (1) Legal name and address of performing organization or institution to which the Director has issued an award under the terms of this request for applications;
- (2) Title of project;
- (3) Name(s) and institution(s) of PDs chosen to direct and control approved activities;
- (4) Identifying award number assigned by the Department;
- (5) Project period, specifying the amount of time the Department intends to support the project without requiring re-competition for funds;
- (6) Total amount of Departmental financial assistance approved by the Director during the project period;
- (7) Legal authority(ies) under which the award is issued;
- (8) Appropriate Catalog of Federal Domestic Assistance (CFDA) number;
- (9) Applicable award terms and conditions (see <http://www.nifa.usda.gov/business/awards/awardterms.html> to view NIFA award terms and conditions);
- (10) Approved budget plan for categorizing allocable project funds to accomplish the stated purpose of the award; and

(11) Other information or provisions deemed necessary by NIFA to carry out its respective awarding activities or to accomplish the purpose of a particular award.

C. Administrative and National Policy Requirements

Several Federal statutes and regulations apply to grant applications considered for review and to project grants awarded under this program. These include, but are not limited to:

7 CFR Part 1, subpart A—USDA implementation of the Freedom of Information Act.

7 CFR Part 3—USDA implementation of OMB Circular No. A-129 regarding debt collection.

7 CFR Part 15, subpart A—USDA implementation of Title VI of the Civil Rights Act of 1964, as amended.

7 CFR Part 331 and 9 CFR Part 121—USDA implementation of the Agricultural Bioterrorism Protection Act of 2002.

7 CFR Part 3015—USDA Uniform Federal Assistance Regulations, implementing OMB directives (i.e., OMB Circular Nos. A-21 and A-122 (2 CFR Parts 220 and 230), and incorporating provisions of 31 U.S.C. 6301-6308 (formerly the Federal Grant and Cooperative Agreement Act of 1977, Pub. L. No. 95-224), as well as general policy requirements applicable to recipients of Departmental financial assistance.

7 CFR Part 3017—USDA implementation of Government-wide Debarment and Suspension (Non-procurement).

7 CFR Part 3018—USDA implementation of Restrictions on Lobbying. Imposes prohibitions and requirements for disclosure and certification related to lobbying on recipients of Federal contracts, grants, cooperative agreements, and loans.

7 CFR Part 3019—USDA implementation of OMB Circular A-110, Uniform Administrative Requirements for Grants and Other Agreements With Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations (2 CFR Part 215).

7 CFR Part 3021—Governmentwide Requirements for Drug Free Workplace (Financial Assistance).

7 CFR Part 3052—USDA implementation of OMB Circular No. A-133, Audits of States, Local Governments, and Nonprofit Organizations.

7 CFR Part 3407—CSREES procedures to implement the National Environmental Policy Act of 1969, as amended.

7 CFR 3415, Biotechnology Risk Assessment Research Grants Program.

7 CFR 3430—Competitive and Noncompetitive Non-formula Grant Programs--General Grant Administrative Provisions.

29 U.S.C. 794 (section 504, Rehabilitation Act of 1973) and 7 CFR Part 15b (USDA implementation of statute) —prohibiting discrimination based upon physical or mental handicap in Federally assisted programs.

35 U.S.C. 200 et seq. —Bayh Dole Act, controlling allocation of rights to inventions made by employees of small business firms and domestic nonprofit organizations, including universities, in Federally assisted programs (implementing regulations are contained in 37 CFR Part 401).

D. Expected Program Outputs and Reporting Requirements

1. Expected Program Outputs

Project Directors are expected to participate in a one- to two-day project director's conference (beginning the second year of the funding) in the metropolitan Washington, DC area or another location (to be determined at a later date). An oral briefing for representatives of a regulatory agency may be scheduled during this time. Reasonable travel expenses may be claimed as part of the project budget.

2. Reporting Requirements

Grantees are to submit initial project information and annual summary reports to NIFA's electronic, Web-based inventory system that facilitates both grantee submissions of project outcomes and public access to information on Federally-funded projects. The details of these reporting requirements are included in the award terms and conditions.

Any additional reporting requirements will be identified in the terms and conditions of the award (see Part VI, B.9. for a link to view the NIFA award terms and conditions).

PART VII—AGENCY CONTACTS

Applicants and other interested parties are encouraged to contact the following National Program Leaders for questions related to the BRAG program:

Dr. Shing F. Kwok; National Program Leader; Institute of Food Production and Sustainability; National Institute of Food and Agriculture; U.S. Department of Agriculture; 800 9th St., SW; Washington, DC 20024; telephone: (202) 401-6060; fax: (202) 401-6071; e-mail: skwok@nifa.usda.gov.

Dr. Mark Mirando; National Program Leader; Institute of Food Production and Sustainability; National Institute of Food and Agriculture; U.S. Department of Agriculture; 800 9th St., SW; Washington, DC 20024; telephone: (202) 401-4336; fax: (202) 401-6071; e-mail: mmirando@nifa.usda.gov.

Dr. Jack Okamuro; National Program Leader - Crop Production and Protection; Agricultural Research Service; U.S. Department of Agriculture; George Washington Carver Center, Room 4-2220; 5601 Sunnyside Avenue; Beltsville, MD 20705-5139; telephone: (301) 504-5912; mobile: (202) 285-9520; e-mail: jack.okamuro@ars.usda.gov.

PART VIII—OTHER INFORMATION

A. Access to Review Information

Copies of reviews, not including the identity of reviewers, and a summary of the panel comments will be sent to the applicant PD after the review process has been completed.

B. Use of Funds; Changes

1. Delegation of Fiscal Responsibility

Unless the terms and conditions of the award state otherwise, the awardee may not in whole or in part delegate or transfer to another person, institution, or organization the responsibility for use or expenditure of award funds.

2. Changes in Project Plans

a. The permissible changes by the awardee, PD(s), or other key project personnel in the approved project shall be limited to changes in methodology, techniques, or other similar aspects of the project to expedite achievement of the project's approved goals. If the awardee or the PD(s) is uncertain as to whether a change complies with this provision, the question must be referred to the Authorized Departmental Officer (ADO) for a final determination. The ADO is the signatory of the award document, not the program contact.

b. Changes in approved goals or objectives shall be requested by the awardee and approved in writing by the ADO prior to effecting such changes. In no event shall requests for such changes be approved which are outside the scope of the original approved project.

c. Changes in approved project leadership or the replacement or reassignment of other key project personnel shall be requested by the awardee and approved in writing by the ADO prior to effecting such changes.

d. Transfers of actual performance of the substantive programmatic work in whole or in part and provisions for payment of funds, whether or not Federal funds are involved, shall be requested by the awardee and approved in writing by the ADO prior to effecting such transfers, unless prescribed otherwise in the terms and conditions of the award.

e. The project period may be extended by NIFA without additional financial support, for such additional period(s) as the ADO determines may be necessary to complete or fulfill the purposes of an approved project, but in no case shall the total project period exceed any applicable statutory limit or expiring appropriation limitation. Any extension of time shall be conditioned upon prior request by the awardee and approval in writing by the ADO, unless prescribed otherwise in the terms and conditions of award.

f. Changes in Approved Budget: Unless stated otherwise in the terms and conditions of award, changes in an approved budget must be requested by the awardee and approved in writing by the

ADO prior to instituting such changes, if the revision will involve transfers or expenditures of amounts requiring prior approval as set forth in the applicable Federal cost principles, Departmental regulations, or award.

C. Confidential Aspects of Applications and Awards

When an application results in an award, it becomes a part of the record of NIFA transactions, available to the public upon specific request. Information that the Secretary determines to be of a confidential, privileged, or proprietary nature will be held in confidence to the extent permitted by law. Therefore, any information that the applicant wishes to have considered as confidential, privileged, or proprietary should be clearly marked within the application. The original copy of an application that does not result in an award will be retained by the Agency for a period of three years. Other copies will be destroyed. Such an application will be released only with the consent of the applicant or to the extent required by law. An application may be withdrawn at any time prior to the final action thereon.

D. Regulatory Information

For the reasons set forth in the final Rule related Notice to 7 CFR part 3015, subpart V (48 FR 29114, June 24, 1983), this program is excluded from the scope of the Executive Order 12372 which requires intergovernmental consultation with State and local officials. Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the collection of information requirements contained in this Notice have been approved under OMB Document No. 0524-0039.

E. Definitions

Please refer to 7 CFR 3415, Biotechnology Risk Assessment Research Grants Program, and 7 CFR 3430, Competitive and Noncompetitive Non-formula Grant Programs--General Grant Administrative Provisions, for the applicable definitions for this NIFA grant program. If a conflict exists between these regulations, the language in 7 CFR 3415 is overriding.